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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,162	06/04/2001	Jason Koontz	05311-024001	5882

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EXAMINER	
CANELLA, KAREN A	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 11/10/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/874,162	KOONTZ ET AL.	
	Examiner	Art Unit	
	Karen A Canella	1642	

-- The MAILING DATE of this communicati n appears on the c ver sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) *1-18,20-31,36 and 37* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *19,32-35 and 38-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8, 11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Acknowledgement is made of applicant election without traverse of Group II, drawn to JAZ polypeptides in the paper filed April 7, 2003 and the election of SEQ ID NO:5 in the paper filed August 20, 2003. After review and reconsideration, the requirement for the election of the SEQ ID NO as a separate invention is withdrawn and replaced as a requirement for a separate species. Upon notification that a generic claim is allowable, consideration will be given to the remaining species of SEQ ID NO:2 and SEQ ID NO:8.

2. Claims 36, 37 have been amended. Claims 39-42 have been added. Claims 1-17 and 21-31, drawn to non-elected inventions, are withdrawn from consideration. Claims 18, 20, 36, 37, drawn to non-elected species, are withdrawn from consideration. Claims 19, 32, 33, 34, 35, 38-42 are examined on the merits to the extent that the claims read on SEQ ID NO:5.

Specification

3. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. The specification contains browser executable code on page 8, lines 15 and 19, and page 9, line 10.

Claim Objections

4. Claim38 is objected to because of the following informalities: Claim 38 contains two sentences: "The JAZ polypeptide of claim 32 in which said polypeptide specifically reacts with antibody 9E10"; and "An isolated polypeptide that specifically reacts with antibody 9E10". For purpose of examination, only the first sentence will be considered.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 33-35 and 38-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claims 33 and 39 recite "substantially identical". The metes and bounds of what constitutes "substantially identical" versus noon-substantially identical cannot be determined. for instance, substantially identical might be equated with 99%, 95%, 90%, 80%, 50% or 30% sequence homology, and it is unclear where applicant intends the border of "substantially identical" to lie in reference to "non-substantially identical".

(B) Claims 34 and 40 recite "stringent hybridization conditions". The metes and bounds of what constitutes "stringent hybridization conditions" are not defined by the specification. The examples of stringent hybridization on page 5, line 24 to page 6, line 6 cannot be construed as a limiting definition of "stringent hybridization" as these examples are specific embodiments rather than limiting definitions.

(C) Claim 38 is vague and indefinite in the recitation of 9E10 as the only means for identifying the antibody which binds to the claimed polypeptide. The use of laboratory designations only to identify an antibody is vague and indefinite because different laboratories use the same designations to identify completely different antibodies or hybridomas. Incorporation of a deposit accession number for the antibody would overcome this rejections because deposit accession numbers are unique identifiers.

(D) It is unclear how claim 38 further limits claim 32, because the 9E10 antibody is recognized in the art as binding to a c-myc epitope, and this is corroborated by the instant specification which uses the 9E10 antibody to isolate myc-tagged polypeptides (page 55, line 21).

(E) Claims 35 and 41 are rendered vague and indefinite in the recitation of "a portion" of a sequence. It is unclear whether "a portion" of a sequence refers to a contiguous or dis-contigous segment of SEQ ID NO:5. For purpose of examination, both alternatives will be considered..

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 32, 33, 34, 35, 38, , 39, 40, 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to isolated JAZ polypeptides, and polypeptide variants of said JAZ polypeptides. Thus the claims encompass a genus of JAZ polypeptides. The specification describes three JAZ polypeptides of SEQ ID NO:2, 5 and 8. The specification states that the name "JAZ" refers to "juxtaposed with another zinc finger" and that said polypeptides are expressed from genes expressed as a result of a chromosomal translocation of (7;17) (p15; q21). thus the claims are drawn to mutant gene sequences which are formed as a result of chromosomal breakage and rejoining. the specification describes three such genes. However, the description of said three polypeptides does not describe the relationship between the structure of the polypeptides, or the genes encoding said polypeptides and the structure of any other polypeptides produced from said chromosomal translocation. the general knowledge in the art does not recognize that the structure of one protein expressed as a result of a translocation event does not provide any indications as to the structure of other proteins expressed as a result of the same translocation event. the nature of proteins which are upregulated by being placed into proximity with a promoter by means of a translocation event, or the nature of proteins expressed from new coding sequences formed as a result of a translocation event is that said proteins are variant structures and in the present state of the art, the structure of one does not provide guidance to the structures of others. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of three members of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claims 32 and 38 are rejected under 102(b) as being anticipated by the abstract of Ambros (Materia Medica Polona, 1992, Vol. 24, pp. 76-78) as evidenced by the abstract of Chan et al (Molecular and Cellular Probes, 1987, vol. 1, pp. 73-82) and the abstract of Sonobe et al (Cancer Genet Cytogenet, 1999 Jul, Vol. 112, pp. 34-37). Claim 32 is drawn to a JAZ polypeptide. Claim 38 embodies the polypeptide of claim 32 wherein said polypeptide specifically reacts with the 9E10 antibody. It is noted that both claims 32 and 38 are rejected for being vague and indefinite under 112, second paragraph, above.

Ambros disclose that high c-myc, also known as p62, expression is variably expressed in endometrial carcinoma and high myc expression is associated with populations of tumor cells selectively capable of myometrial and vascular invasion. Ambros disclose that normal endometrial stromal cells were negative for c-myc staining. Chan et al disclose that the 9E10 antibody specifically bids to the 62 kDa c-myc gene product in tumor cells. The specification teaches that the JAZ proteins are formed by fusions of genes after a (7;17) (p15; q21) chromosomal translocation (page 2, lines 10-14) and that the protein fusions are present in endometrial stromal tumors but not in normal endometrium and are therefore useful for the detection of the endometrial stromal tumors. The abstract of Sonobe et al disclose that the (7:17)

translocation was documented in 4 of the 11 chromosomal abnormalities associated with endometrial stromal carcinomas. Thus it appears that expression of c-myc could result from the (7;17) (p15; q21) translocation. IN RE BEST INSERTION. Based on the expression of c-myc in a population of endometrial tumor cells and the lack of expression of c-myc in normal endometrial stromal cells, and based on the binding of the 9E10 antibody to c-myc, it is concluded that c-myc fulfills the specific embodiment of the JAZ polypeptide of claim 32.

11. Claim 32 is rejected under 102(a) as being anticipated by the abstract of Chu et al (American Journal of Clinical Pathology, 2000 March, Vol. 113, pp. 374-382) as evidenced by the abstract of Sonobe et al (Cancer Genet Cytogenet, 1999 Jul, Vol. 112, pp. 34-37). The specific embodiments of the claim is set forth above. Chu et al disclose the CD10 antigen as a specific protein marker for endometrial stromal cell carcinoma. The specification teaches that the JAZ proteins are formed by fusions of genes after a (7;17) (p15; q21) chromosomal translocation (page 2, lines 10-14) and that the protein fusions are present in endometrial stromal tumors but not in normal endometrium and said proteins are therefore useful for the detection of the endometrial stromal tumors. The abstract of Sonobe et al disclose that the (7:17) translocation was documented in 4 of the 11 chromosomal abnormalities associated with endometrial stromal carcinomas. Thus it appears that expression of the CD10 antigen could result from the (7;17) (p15; q21) translocation. IN RE BEST INSERTION. Based on the association of CD10 with endometrial stromal tumors but not with normal endometrium, it is reasonable to conclude that CD10 is a JAZ polypeptide.

12. Claims 32, 33, 34, 35, 39, 40 and 41 are rejected under 35 U.S.C.102(e) as being anticipated by Rosen et al WO 01/55322 (priority to January 31, 2001). Claim 32 is drawn to an isolated JAZ polypeptide. Claim 33 embodies the JAZ protein of claim 32 in which said polypeptide is substantially identical to SEQ ID NO:5. Claim 34 embodies the polypeptide of claim 32 which is encoded by a nucleic acid molecule comprising a nucleotide sequence which hybridizes under stringent conditions to SEQ ID NO:4 or SEQ ID NO:6. Claim 35 is drawn in part to a polypeptide comprising a portion of SEQ ID NO:5, said portion being at least 30% of SEQ ID NO:5. Claim 39 embodies the polypeptide of claim 33 wherein said polypeptide is

substantially identical to SEQ ID NO:5. Claim 40 embodies the polypeptide of claim 34 wherein said polypeptide is encoded by a nucleic acid sequence which hybridizes under stringent conditions to a nucleic acid molecule comprising SEQ ID NO:4 or SEQ ID NO:6. Claim 41 is drawn to a polypeptide comprising a portion of SEQ ID NO:5, said portion being at least 30% of SEQ ID NO:5.

Rosen et al disclose the polypeptide of SEQ ID NO:931 wherein said polypeptide has 100% identity to a portion of SEQ ID NO:5, wherein said portion is 52.6% of SEQ ID NO:5 as evidenced by the attached sequence alignment (AAU15978). It is noted that claims 35 and 41 were rejected under 112, second paragraph for the recitation of "a portion" because it was not clear if "a portion" referred to a contiguous or a non-contiguous segment of SEQ ID NO:5. Further, the nucleic acid sequence encoding residues 1-388 of SEQ ID NO:931 would hybridize under stringent conditions to either of SEQ ID NO:4 or SEQ ID NO:6. Claims 34 and 40 require only that the nucleotide sequence hybridizes under stringent conditions to SEQ ID NO:4 or SEQ ID NO:6, not that the nucleic acid molecule comprising said nucleotide sequence would hybridize to SEQ ID NO:4 or 6. Additionally, it is noted that claims 33 and 39 are rejected under 112, second paragraph because the metes and bounds of "substantially identical" cannot be determined. thus, the polypeptide of SEQ ID NO:931 as disclosed by Rosen et al is considered as substantially identical to SEQ ID NO:5 because it comprises a amino acid sequence having 99.5% local similarity to SEQ ID NO:5.

Claims 19, 32-35 and 39-41 are rejected under 102(b) as being anticipated by the abstract of Nagase et al (DNA Research, 1995, Vol. 2, pp. 167-174) as evidenced by the alignment with Accession number Q15022 (attached). The specific embodiments of claims 32-35, 39, 40 and 41 are set forth above. Claim 19 is drawn to an isolated polypeptide of SEQ ID NO:5.

The abstract of Nagase et al disclose the polypeptide encoded from the coding sequence of a human gene wherein said polypeptide is 100% identical to SEQ ID NO:5.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner

can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
11/03/03